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PATENT

Attorney Docket No. 16930-001022

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Douglas Antelman, *et al.*

Application No.: 09/315,116

Filed: May 19, 1999

For: METHODS OF TREATING HYPERPROLIFERATIVE DISORDERS USING RETINOBLASTOMA FUSION PROTEINS

Examiner: M. Davis

Art Unit: 1642

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office communication mailed April 22, 2002, Applicants elect, with traverse, to prosecute the claims of Group II, claims 16, 17-30 and 37, drawn to a method for treating a hyperproliferative disorder, comprising administering a nucleic acid encoding a fusion protein comprising a DNA binding domain of a transcriptional factor and a functional growth suppression domain of a retinoblastoma (RB) polypeptide. Further, in response to the Species Elections, Applicants elect the species wherein the transcription factor is E2F and the E2F polypeptide comprises about amino acid 95 to about amino acid 194 of SEQ ID NO:1, and the species wherein the RB polypeptide comprises about from amino acid residue 379 to 928 of SEQ ID NO:4.

Applicants respectfully traverse the Restriction Requirement on at least two grounds. First, the Restriction Requirement does not follow the procedure set forth in 37 CFR § 1.141-1.146 and the corresponding sections of the MPEP for handling generic claims. According to 37 CFR § 1.141, an applicant may not claim two or more independent and distinct inventions in a single application "except that more than one species of an invention . . . may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form or otherwise include all the limitations of the generic claim" (emphasis added). Thus, "[w]here an application contains a generic claim for all of the disclosed species, a restriction usually is not proper." *R2 Medical Systems, Inc. v. Katecho, Inc.*, 931 F. Supp. 1397, 1436, n. 16, n. 17 (N.D. Ill. 1996).

The procedure for handling applications that include generic claims is set forth in 37 CFR § 1.146. This rule provides that "[i]n the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable." As stated in MPEP § 809.02(a), "[u]pon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141." Thus, where generic claims are present, an applicant can be required to elect a species for initial examination, but the generic claims are still subject to examination to determine whether such generic claims are allowable.

In the instant case, the required procedure is not being followed. Claim 16 is a ***proper*** generic claim within the requirements set forth in 37 CFR § 1.141. In the Restriction Requirement, the Examiner alleges that the "generic linking claim 16 is improper, because different members of the claims are patentably distinct and thus not linked to each other" (*see*, page 2 of the Restriction Requirement). However, claim 16 satisfies the definition of a generic claim as set forth in MPEP § 806.04(d), in that this generic claim does not include limitations that are not present in all claims that depend from it. Therefore, claim 16 is, in fact, a proper

generic claim. As such, in the present case, an election of species requirement is permissible, but a restriction requirement is not.

Moreover, because the restriction requirement splits a single claim, *i.e.*, claim 16, into multiple groups, *i.e.*, ***four*** groups, the restriction requirement is improper as a matter of law. The courts have long held that the section of the patent statute that authorizes restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a rejection on a single claim, even if the claim presents multiple independently patentable inventions. *See, In re Weber*, 198 USPQ 328, 331 (CCPA 1978); *In re Haas*, 179 USPQ 623, 624-625 (*In re Haas I*) (CCPA 1973) and *In re Haas* 198 USPQ 334-337 (*In re Haas II*) (CCPA 1978). As stated in *In re Weber*:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim—no matter how broad, which means no matter how many independently patentable inventions may fall within it. 198 USPQ 328 at 334.

As such, the Examiner's statement that "the generic linking claim 16 is improper, because different members of the claims are patentably distinct and thus not linked to each other" is not proper grounds for issuing a restriction requirement (*see*, page 2 of the Restriction Requirement). Again, as mentioned above, the courts have long held that the section of the patent statute that authorizes restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a rejection on a single claim, even if the claim presents multiple independently patentable inventions.

Moreover, in a case such as the instant case, where a claim is generic, a Restriction Requirement is tantamount to a rejection of the claim. The CCPA made this point very clear in *In re Haas I*:

> We find that the action taken by the examiner did in fact amount to a rejection. . . . Those claims were withdrawn from consideration not only in this application but prospectively in any subsequent application because of their content. In effect there had been a denial of patentability of the claims. Presumably only by dividing the subject matter into separate, and thus different, claims in plural applications could an examination of the patentability of their subject matter be obtained. 179 USPQ at 625.

If the instant Restriction Requirement is allowed to stand, Applicants will never be accorded "the basic right of the applicant to claim his invention as he chooses." *In re Weber*, 198 USPQ at 331. In *In re Weber*, the CCPA stated that "[a]s a general proposition, an applicant has a right to have *each* claim examined on the merits" (198 USPQ at 331, emphasis in original). The Court went on to state that:

> If . . . a single claim is required to be divided up and presented in different applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification." 198 USPQ at 331.

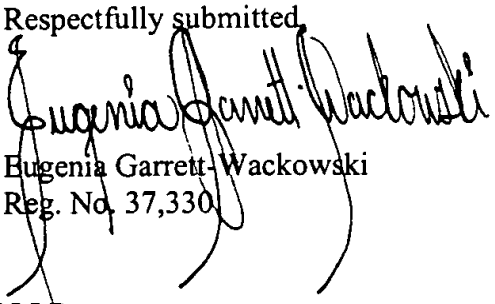
Even if Applicants were to file ***four*** divisional applications to obtain coverage for the claims in each of the ***four*** groups set forth in the Restriction Requirement, they would not have the opportunity to have their broader claim examined. The claims of the ***four*** divisional applications would be limited to the particular species set forth in each of the ***four*** respective groups. In effect, the Restriction Requirement is reading into Applicants' independent claim limitations that are not present in the claim as filed. Claim 16, for example, would never be considered under the current Restriction Requirement. Only the dependent claims which are set forth in the respective groups would be examined.

For at least the foregoing two reasons, the Restriction Requirement set forth by the Examiner is improper and should be withdrawn.

Notwithstanding the foregoing, pursuant to 37 C.F.R. § 1.144, Applicants reserve the right to petition for review of the Restriction Requirement at any time prior to appeal. Applicants also note that because the instant rejection is tantamount to a rejection of the generic claim, the restriction requirement is appealable to the Board of Patent Appeals and Interferences. *In re Haas, supra.*

If the Examiner has any questions regarding Applicants' election, or if the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (925) 472-5000.

Respectfully submitted,



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